DI-5954 (BXTR 9004.6)
PATENT

REPLY UNDER 37 CFR 1.116-EXPEDITED PROCEDURE-TECHNOLOGY CENTER 1654

AMENDMENTS TO THE CLAIMS

1-15. (Cancelled)

16. (Currently amended) A stable pharmaceutical composition comprising erythropoietin and a peptide stabilizer selected from the group consisting of Gly-Gly, Gly-Gly-Gly, Gly-Tyr, Gly-Phe, Gly-His, Gly-Asp, Gly-Ala, Ala-Gly, Ala-Ala, derivatives thereof and mixtures thereof, ~~and~~ wherein the composition is free of serum albumin **and wherein the derivatives are selected from the group consisting of acylated, alpha-keto and salt forms of said peptide stabilizers**.

17. (Cancelled)

18. (Withdrawn) The composition of claim 16, wherein the peptide stabilizer is a tripeptide.

19. (Cancelled)

20. (Previously presented) The composition of claim 16, wherein the derivatives comprise salts of Gly-Gly, Gly-Gly-Gly, Gly-Tyr, Gly-Phe, Gly-His, Gly-Asp, Gly-Ala, Ala-Gly, and Ala-Ala.

21. (Original) The composition of claim 16, wherein concentration of the peptide stabilizer in said composition is between about 0.01 g/L and about 10 g/L.

22. (Original) The composition of claim 21, wherein the concentration of the peptide stabilizer is between about 0.5 g/L and about 5 g/L.

23. (Cancelled)

24. (Original) The composition of claim 16, wherein the erythropoietin is a recombinant erythropoietin.

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25. (Original) The composition of claim 24, wherein the recombinant erythropoietin is produced in BHK cells.

26. (Original) The composition of claim 24, wherein the recombinant erythropoietin is produced in CHO cells.

27. (Original) The composition of claim 24, wherein the recombinant erythropoietin is erythropoietin omega.

28. (Original) The composition of claim 27, wherein concentration of erythropoietin omega in said composition is between about 500 IU/ml and about 100,000 IU/ml.

29. (Original) The composition of claim 28, wherein the concentration of erythropoietin omega is between about 2,000 IU/ml and about 20,000 IU/ml.

30. (Original) The composition of claim 16, wherein the composition further comprises a surfactant.

31. (Original) The composition of claim 30, wherein the surfactant is a nonionic surfactant, cationic surfactant, anionic surfactant, amphoteric surfactant, zwitterionic surfactant, or a mixture thereof.

32. (Cancelled).

33. (Original) The composition of claim 30, wherein concentration of the surfactant in said composition is between about 0.0005% w/v and about 0.5% w/v.

34. (Currently amended) A stable pharmaceutical composition comprising erythropoietin, a polyoxyalkylene sorbitan fatty acid ester, and a peptide stabilizer selected from the group consisting of Gly-Gly, Gly-Gly-Gly, Gly-Tyr, Gly-Phe, Gly-His, Gly-Asp, Gly-Ala, Ala-Gly, Ala-Ala, derivatives thereof and mixtures thereof, wherein

the composition is free of serum albumin **and wherein the derivatives are selected from the group consisting of acylated, alpha-keto and salt forms of said peptide stabilizers**.

35. (Original) The composition of claim 34, wherein the erythropoietin is erythropoietin omega.

36. (Cancelled)

37. (Currently amended) A stable pharmaceutical composition comprising erythropoietin and a peptide stabilizer selected from the group consisting of Gly-Gly, Gly-Gly-Gly, Gly-Tyr, Gly-Phe, Gly-His, Gly-Asp, Gly-Ala, Ala-Gly, Ala-Ala, derivatives thereof and mixtures thereof, ~~and~~ wherein the composition is free of serum albumin and is for administration by parenteral injection **and wherein the derivatives are selected from the group consisting of acylated, alpha-keto and salt forms of said peptide stabilizers**.

38. (Withdrawn) A stable pharmaceutical composition comprising erythropoietin and a peptide stabilizer selected from the group consisting of tetrapeptides, pentapeptides, derivatives thereof and mixtures thereof, and wherein the composition is free of serum albumin.

39. (Withdrawn) The composition of claim 38 wherein the composition is for administration by parenteral injection.

40. (Withdrawn) The composition of claim 38 wherein the composition further comprises a polyoxyalkylene sorbitan fatty acid ester.